***NOT FOR PUBLICATION***

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| REBECCA DANDY,<br><br>Plaintiff,<br><br>v.<br><br>ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of ETHICON, INC., GYNECARE, a Division of ETHICON, INC., ETHICON, INC., and JOHNSON & JOHNSON,<br><br>Defendants. | Civ. Action No. 20-00431 (FLW)<br><br>**OPINION** |

**WOLFSON, Chief Judge:**

This matter concerns product liability claims plaintiff Rebecca Dandy ("Plaintiff") brought in response to injuries she allegedly sustained from a pelvic mesh product manufactured by defendants Ethicon, Inc. and its division, Ethicon Women's Health and Urology ("Defendants" or "Ethicon"). Plaintiff asserts claims for design defect, manufacturing defect, and failure to warn. Defendants filed a motion to exclude testimony from Plaintiff's case-specific expert pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), concerning certain alternative product designs that are allegedly safer than the product Plaintiff received ("*Daubert* Motion"). Defendants also filed a Motion for Summary Judgment on each of Plaintiff's claims. Defendants move for summary judgment on the design defect claim based only on Plaintiff's purported failure to propose a safer alternative design, which Plaintiff must establish to state a claim for design defect, and they move for summary judgment on the failure to

warn claim based only on Plaintiff's purported failure to establish proximate causation. Plaintiff opposes both motions, except she does not oppose summary judgment on her manufacturing defect claim.[1]

For the reasons set forth herein, Defendants' *Daubert* Motion is **GRANTED** in part and **DENIED** in part, and their Motion for Summary Judgment is **GRANTED** in part and **DENIED** in part. The Motion for Summary Judgment is granted with respect to the manufacturing defect and failure-to-warn claims, and it is denied with respect to the design defect claim.

## I. BACKGROUND AND PROCEDURAL HISTORY

In accordance with L. Civ. R. 56.1(a), Defendants filed a Statement of Material Facts with their Motion for Summary Judgment, and Plaintiff filed both a Response to Defendants' Statement of Material Facts ("Pl. Resp. SOMF") and a Statement of Additional Material Facts ("Pl. Supp. SOMF") with her Opposition brief, ECF No. 86-3. Defendants filed a Response to Plaintiff's Statement of Additional Material Facts. ECF No. 89 ("Def. Resp. SOMF"). The following factual and procedural background reflects the undisputed facts from the parties' submissions that are relevant and material to the present motions.

Ethicon manufactures the Tension-free Vaginal Tape-Obturator ("TVT-O) sling, a polypropylene mesh product that is surgically implanted in the pelvic region to treat stress urinary incontinence ("SUI"). SUI "is the involuntary leakage of urine during moments of physical activity

[1] Plaintiff's Amended Complaint names Johnson & Johnson ("J&J") as a defendant, but Defendants' Motion for Summary Judgment and Statement of Material Facts assert that J&J is improperly named as a defendant because it "does not develop, design, manufacture, market, or sell any products or services to the public." ECF No. 73 at 7 n.1; ECF No. 72-12, Defendants' Rule 56.1 Statement of Undisputed Material Facts ("Def. SOMF") at 1. Likewise, Defendants' Motion for Summary Judgment notes that Ethicon Women's Health and Urology is incorrectly named as Gynecare. ECF No. 73 at 7. Plaintiff does not respond to Defendants' position, and in her opposition, she refers repeatedly to Ethicon's Motion for Summary Judgment. *See* ECF No. 83. Accordingly, this Opinion refers to Ethicon, Inc. and Ethicon Women's Health and Urology as the only defendants.

that increases abdominal pressure." *See* ECF No. 85-3 Ex. H, Rule 26 Expert Report of Bruce Rosenzweig M.D. at 4, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litigation*, Civ. No. 12-02327, MDL No. 2327 (S.D. W. Va. May 22, 2017) ("Rosenzweig Gen. TVT-O Rep."); *Stress Urinary Incontinence*, Food & Drug Admin. (Apr. 16, 2019), https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/stress-urinary-incontinence-sui (last visited April 18, 2022). On March 7, 2011, Dr. William E. Nowak implanted a TVT-O sling in Plaintiff's pelvic region to treat her SUI at Munson Medical Center in Traverse City, Michigan. Def. SOMF ¶ 3; Pl. Supp. SOMF ¶ 1. Plaintiff was a resident of Michigan at that time and has remained a resident of Michigan since her surgery.

For several years following her TVT-O implantation surgery, Plaintiff periodically notified healthcare professionals that she was experiencing groin and lower abdominal pain, vaginal discharge, and pain during sexual intercourse (dyspareunia), among other symptoms. *See* ECF No. 70-2 Ex. A, Case Specific Expert Report of Bruce Rosenzweig, M.D. ("Rosenzweig Rep.") at 25–34. In a report Plaintiff produced during discovery, her case-specific expert, Dr. Bruce Rosenzweig,[2]

[2] Defendants assert in their Response to Plaintiff's Statement of Additional Material Facts that Plaintiff may not rely on Dr. Rosenzweig's report because it is unsworn. *See* Def. Resp. SOMF at 4. The Third Circuit recently held that "to create an issue of fact on summary judgment," a statement must either be "sworn," as was required under Rule 56 before it was amended in 2010, or it must be given "under the penalty of perjury," as is now permissible following the 2010 amendment. *See United States ex rel. Doe v. Heart Solution, PC*, 923 F.3d 308, 315–16 (3d Cir. 2019); *see also Lewis v. Pennsylvania*, 609 F. Supp. 2d 409, 420 n.6 (W.D. Pa. 2008) (citing *Fowle v. C&C Cola*, 868 F.2d 59, 67 (3d Cir. 1989)) (holding under pre-2010 Rule 56 that an expert report that is not sworn or attached to a sworn affidavit from the expert was not admissible for purposes of opposing summary judgment motion). Dr. Rosenzweig's report is signed, but it is neither sworn nor given under penalty of perjury. However, this appears to be a clerical error, as the report Dr. Rosenzweig submitted in the MDL is given "under penalty of perjury." *See* Rosenzweig Gen. TVT-O Rep. at 116. Moreover, a court may consider "[a]n unsworn expert report . . . if it was included in the opposing party's summary judgment papers," as courts have held that "inclusion of the report . . . waive[s] any objection to its consideration." 11 Moore's Federal Practice–Civil § 56.94(4)(a) (2022) (citing *Capobianco v. City of New York*, 422 F.3d 47, 55 (2d Cir. 2005)). Here, Defendants submitted Dr. Rosenzweig's report with their moving papers. *See* ECF No. 72 Ex. B. And other courts have held that under "[n]ew Rule 56(c), added in 2010," a party may support or dispute summary judgment

opines that Plaintiff sustained injuries following her surgery that include "pelvic pain, hip pain, pelvic floor muscle spasm, vaginal pain, dyspareunia, recurrent [urinary tract infections], voiding dysfunction, [and] mixed [urinary infection]." Rosenzweig Rep. at 49. Dr. Rosenzweig opines that polypropylene mesh can lead to the injuries Plaintiff incurred through mechanisms such as mesh "degradation" and "chronic foreign body reaction." *See, e.g.*, *id.*; Rosenzweig Gen. TVT-O Rep. at 19; Pl. Supp. SOMF ¶¶ 3–6. Dr. Rosenzweig also opines that heavier, smaller-pore mesh—a characterization he applies to the Prolene mesh used in a TVT-O sling—may cause similar complications because the pores do not allow sufficient room for tissue to regrow properly. *See* Rosenzweig Gen. TVT-O Rep. at 27–32;[3] Rosenzweig Rep. 50. Defendants dispute Dr. Rosenzweig's opinions on both points. *See* Def. Resp. SOMF at 6–15.[4]

In 2019, Plaintiff was also diagnosed with pudendal neuralgia, which occurs when the pudendal nerve—a major nerve that runs from the back of the pelvis to the base of the vagina—becomes injured or irritated. *See Pudendal Neuralgia*, Nat'l Insts. of Health (Jan. 17, 2017), https://rarediseases.info.nih.gov/diseases/10713/pudendal-neuralgia/ (last visited Apr. 18, 2022);

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using unsworn expert reports "provided their contents can be presented in admissible form at trial." *Patel v. Texas Tech. Univ.*, 941 F.3d 743, 746–47 (5th Cir. 2019). Aside from their Rule 702 objections, Defendants do not dispute that the contents of Dr. Rosenzweig's report would be admissible through testimony at trial. Accordingly, I rely on Dr. Rosenzweig's report in this Opinion. Within seven (7) days of the date of the accompanying Order, Plaintiff must submit either a version of Dr. Rosenzweig's report that is sworn or given under penalty of perjury, or an affidavit from Dr. Rosenzweig that is sworn or given under penalty of perjury and that attaches his report. *See Heart Solution*, 923 F.3d at 315–16; *Lewis*, 609 F. Supp. 2d at 420 n.6.

[3] Defendants also contend that the Court may not consider the report Dr. Rosenzweig submitted in the MDL because it is unsworn. *See* Def. Resp. SOMF at 4. However, that report was provided under penalty of perjury, *see* Rosenzweig Gen. TVT-O Rep. at 116, and thus satisfies Rule 56. *See Heart Solution, PC*, 923 F.3d at 315–16.

[4] Whether the TVT-O caused Plaintiff's injuries is not directly at issue on the present motions, but the injuries that a TVT-O may cause are relevant to the safer alternatives Dr. Rosenzweig proposes, which are at issue.

Rosenzweig Rep. at 33, 36, 49. In his report, Dr. Rosenzweig explains that surgeons implant the TVT-O sling using a transobturator procedure, in which the sling must "run through the obturator internus muscle as it passes into the groin." *See* Rosenzweig Rep. at 10. According to Dr. Rosenzweig, running the sling through the obturator muscle can cause obturator internus muscle spasm and entrapment of the pudendal nerve, which can lead to pudendal neuralgia. *See id.* at 10–11.

Following advice from another healthcare professional, on March 4, 2020, Plaintiff underwent surgery to remove the TVT-O mesh sling. Rosenzweig Rep. at 33–34. After the mesh removal surgery, Plaintiff's pain subsided moderately, but her SUI worsened. *See id.* at 35–38.

On June 6, 2019, before undergoing mesh removal surgery, Plaintiff filed a Complaint in the U.S. District Court for the Eastern District of Pennsylvania, asserting sixteen counts pertaining to the TVT-O sling she received in 2011. ECF No. 1. Defendants filed a Motion to Dismiss for lack of personal jurisdiction or, in the alternative, a transfer in venue to the U.S. District Court for the Western District of Michigan or the Eastern District of Michigan. ECF No. 3. The court denied Defendants' motion as moot and transferred the case to this Court pursuant to 28 U.S.C. § 1406(a). ECF No. 10. Defendants filed a Motion to Dismiss certain counts of the Complaint, but before the Court ruled on Defendants' motion, the parties entered into a stipulation under which Defendants withdrew their Motion to Dismiss, and the Court issued a Consent Order setting a deadline for Plaintiff to file an amended complaint, ECF No. 22, which was filed on February 27, 2020. ECF No. 25.

The Amended Complaint asserts one count alleging that Defendants were negligent in designing, manufacturing, labeling, marketing, selling, and distributing the TVT-O sling she received in 2011, without specifying whether Plaintiff asserts the claim under a particular state's products liability statute or the common law. *See id.* at 9. Ethicon and J&J filed separate Answers

to the Amended Complaint. ECF Nos. 27, 28. During discovery, Plaintiff disclosed Dr. Rosenzweig as a case-specific expert and produced Dr. Rosenzweig's report. Defendants filed a *Daubert* Motion seeking to exclude Dr. Rosenzweig's opinions concerning certain safer alternative designs compared to the TVT-O, ECF No. 70, which, for reasons discussed *infra*, Plaintiff must prove to establish a design defect as part of her negligence claim. *See* ECF No. 71. The same day, Defendants filed a Motion for Summary Judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. ECF No. 72. Plaintiff timely filed her opposition to the *Daubert* Motion and the Motion for Summary Judgment, ECF Nos. 85, 86, and Defendants filed their replies, ECF Nos. 88, 80.

## II. CHOICE OF LAW

Defendants' motions require the Court to first determine the applicable substantive law. "[I]n a diversity action, a district court must apply the choice of law rules of the forum state to determine what law will govern the substantive issues of a case." *Warriner v. Stanton*, 475 F.3d 497, 499–500 (3d Cir. 2007). Because New Jersey is the forum state, New Jersey's choice-of-law rules apply. *See Noye v. Johnson & Johnson Servs., Inc.*, 765 F. App'x 742, 745 (3d Cir. 2019).

New Jersey's choice of law rules follow the Restatement (Second) of the Conflict of Laws. *See P. V. v. Camp Jaycee,* 197 N.J. 132, 142–43 (2008). "[T]he first step is to determine whether an actual conflict exists." *Id.* at 143. An "actual conflict" exists when choosing between two states' laws would be "outcome determinative." *McCarrell v. Hoffmann-La Roche Inc.,* 227 N.J. 569, 584 (2017) (citing *Rowe v. Hoffmann-La Roche, Inc.,* 189 N.J. 615, 621 (2007)) ("[A] true conflict of law arises when choosing between one or another state's statute of limitations is outcome determinative."); *Camp Jaycee*, 197 N.J. at 143–44 (finding conflict where New Jersey law made charitable organizations immune from most forms of tort liability whereas Pennsylvania law subjected charitable organizations to tort liability). The court must determine whether a conflict exists "on an issue-by-issue basis." *Rowe,* 189 N.J. at 621 (quotations and citations omitted). "If there is no actual

conflict, then the choice-of-law question is inconsequential," and the court would apply the law of the forum state—here, New Jersey— "to resolve the disputed issue." *Id.*

If a conflict exists, "the Court must determine which state has the most significant relationship to the claim, by weigh[ing] the factors set forth in the Restatement section corresponding to the plaintiff's cause of action." *Arlandson v. Hartz Mountain Corp.,* 792 F. Supp. 2d 691, 699 (D.N.J. 2011) (quotations and citation omitted); *Camp Jaycee*, 197 N.J. at 143 (concluding courts must "apply the Second Restatement's most significant relationship standard in tort cases"). "In an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship." *Restatement (Second) of Conflict of Laws* § 146; *Camp Jaycee*, 197 N.J. at 143 ("[T]he law of the state of the injury is applicable unless another state has a more significant relationship to the parties and issues."). To determine whether another state "has a more significant relationship" than the state where the injury occurred, courts must examine "the remaining contacts set forth in sections 145 and . . . 6" of the Restatement. *Camp Jaycee*, 197 N.J. at 144–45. Section 145 provides that, "in applying the principles of § 6," the relevant contacts are: "(a) the place where the injury occurred[;] (b) the place where the conduct causing the injury occurred[;] (c) the domicil, residence, nationality, place of incorporation and place of business of the parties[;] and (d) the place where the relationship, if any, between the parties is centered." *Restatement (Second) of Conflict of Laws* § 145. And, "[r]educed to their essence, the section 6 principles are: (1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." *Camp Jaycee*, 197 N.J. at 147 (internal quotations and citations omitted).

Here, a conflict exists between the applicable products liability laws in New Jersey, where Defendants are incorporated and maintain their headquarters, and Michigan, Plaintiff's home state

and where Dr. Nowak implanted Plaintiff's TVT-O sling. In New Jersey, plaintiffs must bring "claims for 'harm caused by a product'" under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. 2A:58C-1, *et seq*. *Sinclair v. Merck,* 195 N.J. 51, 65–66 (2008) (quoting N.J.S.A. 2A:58C-1(b)(3)) (concluding products liability claim must be brought under the NJPLA because "the Legislature expressly provided . . . that claims for 'harm caused by a product' are governed by the [NJ]PLA 'irrespective of the theory underlying the claim'"); *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 374 (D.N.J. 2019) ("The NJPLA is the 'sole basis of relief under New Jersey law available to consumers injured by a defective product.'") (quoting *Repola v. Morbark Industries, Inc.*, 934 F.2d 483, 492 (3d Cir. 1991)). "[N]egligence and breach of [implied] warranty are [not] viable" as separate claims for injuries caused by defective products. *Oguendo v. Bettcher Industries, Inc.*, 939 F. Supp. 357, 361 (D.N.J. 1996) (citing *Tirrell v. Navistar Intern, Inc.*, 248 N.J. Super. 390, 398 (App. Div. 1991)), *aff'd*, 118 F.3d 1577 (3d Cir.1997). In contrast, Michigan does not recognize strict liability in products liability cases, and instead only recognizes actions for negligence and breach of implied warranty. *Magnant v. Medtronic, Inc.,* 818 F. Supp. 204, 206 (W.D. Mich. 1993) (citing *Prentis v. Yale Mfg. Co.*, 421 Mich. 670, 683 (1984)) (recognizing conflict of law because "Michigan does not accept strict liability" in products liability actions, whereas Minnesota "recognizes claims based on the theory of strict liability in actions against manufacturers for product defects that cause personal injury"); *Hartford Fire Ins. Co. v. Walter Kidde & Co.*, 120 Mich. App. 283, 291 (1982) (holding Michigan only recognizes negligence and breach of implied warranty as causes of action in products liability cases). Thus, while Plaintiff's sole negligence claim is cognizable under Michigan law, it is not permitted under New Jersey law. *See Mills*, 406 F. Supp. 3d at 374–75 (finding conflict where "Pennsylvania law allows negligence and breach of warranty claims, but New Jersey only allows one statutory cause of action for strict liability") (quotations and citations omitted).

Having concluded that a conflict exists, I must apply the law of the state with the "most significant relationship" to this litigation based on the factors set forth in the Restatement. *Arlandson*, 792 F. Supp. 2d at 699. Because the parties agree that Michigan law applies under this standard, my analysis is brief. *See* ECF No. 73 at 9–11; ECF No. 86 at 7–8; ECF No. 90 at 4. There is a strong presumption that Michigan law applies because Plaintiff suffered the injury that Defendants' product allegedly caused in that state. *See Camp Jaycee,* 197 N.J. at 144 ("Section 146 recognizes the intuitively correct principle that the state in which the injury occurs is likely to have the predominant, if not exclusive, relationship to the parties and issues in the litigation."). Dr. Nowak initially implanted the TVT-O in Plaintiff during surgery in Michigan, Def. SOMF ¶ 3, and Plaintiff experienced many of the medical complications that the TVT-O allegedly caused while living in Michigan. *See* Rosenzweig Rep. at 25–34.

New Jersey does not have a more significant relationship than Michigan under the factors set forth in Section 145 of the Restatement. *Camp Jaycee*, 197 N.J. at 144–45. Plaintiff's injuries, and at least a portion of the conduct that allegedly caused her injuries, *see Restatement (Second) of Conflict of Laws* § 145(2)(a)–(b), occurred in Michigan, where she received the TVT-O sling. *See* Def. SOMF ¶ 3; Rosenzweig Rep. at 25–34. Plaintiff is also domiciled in Michigan, and Michigan is where her "relationship" to Defendants is "centered." *See Restatement (Second) of Conflict of Laws* § 145(2)(c)–(d); Def. SOMF ¶¶ 1, 3. While certain conduct that allegedly caused Plaintiff's injuries occurred in New Jersey, where Defendants are headquartered and where they presumably designed the TVT-O, courts within the Third Circuit have concluded repeatedly that, in a products liability action, these contacts typically do not outweigh those of the state where an injury occurs. *See Mills*, 406 F. Supp. 3d at 375–76 (applying law of state—Pennsylvania—where plaintiff resided, used an allegedly defective mesh surgical product, and incurred an injury, and finding one defendant's incorporation in New Jersey insufficient to override Pennsylvania's contacts); *see also Knipe v.*

*SmithKline Beecham*, 583 F. Supp .2d 602, 615–16 (E.D. Pa. 2008). Accordingly, the factors set forth in Section 145 do not weigh in favor of applying New Jersey law.

Nor do the factors under Section 6 tip the balance toward New Jersey. "First, the interests of interstate comity favor applying the law of the individual claimant's own state," as "[a]pplying New Jersey law to every potential out-of-state claimant would frustrate the policies of each claimant's state." *Maniscalco v. Brother Intern. (USA) Corp.*, 709 F.3d 202, 209 (3d Cir. 2013). Second, the parties agree that Michigan law applies, indicating that their interests do not diverge regarding the choice of law. Likewise, because products liability law is premised on the dual policies of compensating injured parties and "regulat[ing] the conduct of manufacturers and distributors," *Mills*, 406 F. Supp. 3d at 375, the "third section 6 factor likely favors neither state." *See Maniscalco*, 709 F.3d at 210. As for the fourth factor, although the interests of judicial administration could favor New Jersey law in order to "further[] the values of uniformity and predictability of result," New Jersey courts have emphasized that "[these] considerations . . . are of lesser importance and must yield to a strong state interest implicated by the remaining factors." *Fu*, 160 N.J. at 124; *Maniscalco*, 709 F.3d at 210 (same). Finally, under the fifth and "most important[]" factor, the Third Circuit has concluded in the analogous consumer fraud context that the "the interest of [a state] in having its law apply to its own consumers outweighs the interests of New Jersey in protecting out-of-state consumers from" tortious conduct that allegedly originates in New Jersey. *Maniscalco*, 709 F.3d at 210. Section 6 therefore does not alter my conclusion that Michigan's substantive law applies to Plaintiff's negligence claim.

## III. *DAUBERT* MOTION

### A. Legal Standard

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. The rule "'has three major requirements: (1) the proffered witness must be an expert, *i.e.*, must be

qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge [, *i.e.*, reliability]; and (3) the expert's testimony must assist the trier of fact [, *i.e.*, fit].'" *United States v. Schiff*, 602 F.3d 152, 172 (3d Cir. 2010) (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir.2008)). In applying Rule 702, "a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda*, 520 F.3d at 243. There is no dispute here as to whether Dr. Rosenzweig is qualified as an expert.

With respect to the second requirement, "an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citing *Daubert*, 509 U.S. at 589). Courts consider several factors in determining whether an opinion is reliable, including:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

*Pineda*, 520 F.3d at 247–48. However, "these factors are neither exhaustive nor applicable in every case." *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 806–07 (3d Cir. 1997).

The third requirement addresses "whether there is a sufficient 'fit' between the expert's testimony and the facts that the jury is being asked to consider." *Schiff*, 602 F.3d at 172–73; *Paoli*, 35 F.3d at 743 (noting that fit concerns "'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case'") (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)). "'[F]it is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.'" *Paoli*, 35 F.3d at 743 (quoting *Daubert*, 509 U.S. at 591). But fit is ultimately "a question of relevance, and 'Rule 702 . . . has a liberal policy of admissibility' if [testimony] has the 'potential for assisting the trier of

fact.'" *Schiff*, 602 F.3d at 173 (quoting *Kannankeril*, 128 F.3d at 806).

**B. Applicable Substantive Law**

Because admissibility under Rule 702 turns in part on the relevance of the expert's testimony, I must first set out the substantive law governing Plaintiff's claims.

Plaintiffs may establish a claim for negligence under Michigan products liability law using several different theories: "(1) design defect; (2) manufacturing defect[;] and (3) failure to warn consumers about a 'defective' product of which the manufacturer has notice." *Croskey v. BMW of N.A.*, 532 F.3d 511, 514–15 & n.1 (6th Cir. 2008). Defendants seek to exclude Dr. Rosenzweig's opinions and proposed testimony only in the context of Plaintiff's design defect claim.[5]

To prove a design defect claim, "a plaintiff must show that (1) the product was not reasonably safe when it left the control of the manufacturer; and (2) a 'feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users.'" *Croskey*, 532 F.3d at 516 (quoting Mich. Comp. Laws § 600.2946(2)). These elements require a "risk-utility" analysis, which "invites the trier of fact to consider the alternatives and risks faced by the manufacturer in designing the product and to determine whether in light of certain factors 'the manufacturer exercised reasonable care in making the design choices it made.'" *Croskey*, 532 F.3d at 516 (quoting *Prentis v. Yale Mfg. Co.*, 421 Mich. 670, 688 (1984)). Michigan's risk-utility test requires a plaintiff to show:

> (1) that the severity of the injury was foreseeable by the manufacturer; (2) that the likelihood of the occurrence of the injury was foreseeable by the manufacturer at the time of distribution of the product; (3) that there was a reasonable alternative design available; (4) that the alternative available design was practicable; (5) that the available and practicable reasonable alternative design would have reduced the

[5] Plaintiff does not oppose Defendants' Motion for Summary Judgment on her manufacturing defect claim, *see* ECF No. 86 at 5 n.1, which is dismissed. I will discuss the standard applicable to claims for failure to warn when addressing the merits of Defendants' Motion for Summary Judgment on that claim, *infra*.

> foreseeable risk of harm posed by the defendant's product; and (6) that the omission of the available and practicable reasonable alternative design rendered the defendant's product not reasonably safe.

*Croskey*, 532 F.3d at 516 (citing *Hollister v. Dayton Hudson Corp.*, 201 F.3d 731, 738 (6th Cir.2000)). Defendants move for summary judgment only on the basis that Plaintiff has failed to propose an available alternative design that is safer and feasible.

A plaintiff bears the burden to establish a safer and feasible alternative design, *see Hollister*, 201 F.3d at 739, which requires expert testimony, *Hendrian v. Safety-Kleen Sys.*, Civ. No. 08-14371, 2015 WL 4770966, at *5 (E.D. Mich. Aug. 13, 2015). Under Michigan law,

> An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

Mich. Comp. Laws § 600.2946(2).

Where a plaintiff "proffers an alternative design that is not currently in use," she bears a "'heavy burden' [to show that] the chosen design was unreasonably dangerous." *Fisher v. Kawasaki Heavy Indus., Ltd.*, 854 F. Supp. 467, 470–71 (E.D. Mich. 1994) (quoting *Owens v. Alice-Chalmers Corp.*, 414 Mich. 413, 430 (1982)). "To satisfy the 'heavy burden' created by *Owens* under such circumstances," the plaintiff must show "that the chosen design was unreasonably dangerous" using "compelling, empirical evidence of an alternative design." *Fisher*, 854 F. Supp. at 471. "Such empirical evidence will probably most often take the form of testing, but must objectively show acceptability, utility, feasibility (including cost), and general safety of the proposed alternative design vis-a-vis the allegedly defective design." *Id.*

**C. Analysis**

Dr. Rosenzweig proposes six alternative designs that, in his opinion, would have been feasible and safer alternatives for Plaintiff compared to the TVT-O: (1) the Burch procedure; (2) an autologous fascia sling; (3) an allograft sling; (4) a sling using UltraPro mesh; (5) a retropubic sling; and (6) a retropubic sling using UltraPro mesh. *See* Rosenzweig Rep. at 19–20, 50–51. For the reasons that follow, Dr. Rosenzweig's opinions concerning the first and second alternatives are inadmissible under Rule 702, but his opinions concerning the third through sixth alternatives are admissible. Plaintiff also contends in her Opposition that Dr. Rosenzweig proposes several other designs, but as discussed *infra*, I find that his reports do not adequately propose these designs as available alternatives that would have reduced the likelihood of Plaintiff's injuries occurring.

*1. Burch Procedure*

The first alternative Dr. Rosenzweig proposes is the Burch procedure. *See* Rosenzweig Rep. at 50. The Burch procedure is a procedure in which surgeons suspend the neck of the bladder from nearby ligaments using sutures. *See* Rosenzweig Gen. TVT-O Rep. at 7; *see also Heatherman v. Ethicon, Inc.*, Civ. No. 20-01932, 2020 WL 5798533, at *9 (D. Colo. Sept. 29, 2020). Defendants seek to exclude Dr. Rosenzweig's opinions concerning the Burch procedure on grounds that, as a matter of law, a surgical procedure does not qualify as an alternative product design, and Dr. Rosenzweig's testimony therefore would not be relevant. *See* ECF No. 71 at 11–12. I agree.

Although the Michigan Supreme Court has not addressed this issue, courts in Michigan and elsewhere are consistent in holding that a surgical procedure generally does not qualify as an alternative design for purposes of a design defect claim. *See, e.g.*, *Barnes v. Medtronic, PLC*, Civ. No. 17-14194, 2019 WL 1353880, at **1–2 (E.D. Mich. Mar. 26, 2019) (concluding in design defect case involving hernia mesh that the "Shouldice surgical procedure" is an "alternative treatment method" and not an "alternative production practice[] or design[]"); *Heatherman*, 2020 WL 5798533, at **8–9 (concluding that alternative medical procedures do not qualify as feasible alternative

product designs); *Pizzitola v. Ethicon, Inc.*, Civ. No. 20-2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020) (concluding that the plaintiff "must propose a safer and feasible alternative design to the alleged defective designs, not different procedures . . . entirely"); *Moultrie v. Coloplast Corp.*, Civ. No. 18-231, 2020 WL 1249354, at *11 n.20 (W.D. Pa. Mar. 16, 2020) (same); *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) ("Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT"). Evidence concerning alternative surgical procedures generally implicates the treating physician's medical judgment and not a manufacturer's choice of product design. *See Heatherman*, 2020 WL 5798533, at *9 ("The existence of alternative *procedures* to the one [the plaintiff] underwent goes to medical malpractice, not to any defect in Ethicon's TVT *product*.") (emphasis in original); *Moultrie*, 2020 WL 1249354, at *11 n.20 (same); *Mullins*, 236 F. Supp. 3d at 943 (same).

The Burch procedure is a surgical procedure and therefore does not qualify as an alternative design for purposes of Plaintiff's design defect claim. *See Heatherman*, 2020 WL 5798533, at *9 (concluding "as a matter of law that the Burch procedure cannot be an alternative product to the TVT"); *Moultrie*, 2020 WL 1249354, at *11 n.20 (concluding that the Burch procedure is a "surgical procedure[] rather than [a] medical device" and therefore does not qualify as a feasible alternative design). To the extent Plaintiff contends that the Burch procedure qualifies as an alternative design because it "requires the use of a device—an absorbable suture—" her position is unavailing, as there is no indication that "the sutures themselves could . . . stand in for the [TVT-O] as an alternative device." *See Heatherman*, 2020 WL 5798533, at *9.

Because the Burch procedure is not a feasible alternative design compared to a TVT-O sling as a matter of law, Dr. Rosenzweig's opinions and testimony concerning the Burch procedure will not assist the jury in determining whether an alternative feasible design was available to Defendants. *See Schiff*, 602 F.3d at 172 (noting that the question of "fit" concerns "'whether [the] expert testimony

proffered . . . is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute'") (quoting *Daubert*, 509 U.S. at 591). Accordingly, Dr. Rosenzweig's opinions and proposed testimony on this point are inadmissible under Rule 702.

*2. Autologous Fascia Sling*

The second alternative Dr. Rosenzweig proposes is an autologous fascia sling, *see* Rosenzweig Rep. at 50, which is a sling created out of tissue harvested from the patient that a surgeon uses to suspend the neck of the bladder. *See* ECF No. 85-3 Ex. C, Deposition of Bruce Rosenzweig, M.D., *Jane Olszeski v. Ethicon, Inc., et al.* ("Rosenzweig *Olszeski* Dep.") Tr. 81:22–82:9;[6] *see also Heatherman*, 2020 WL 5798533, at *9 (noting that in "autologous sling procedures, surgeons harvest tissue from the patient and use the native tissue as a sling to suspend the neck of the bladder"). Defendants move to exclude Dr. Rosenzweig's opinions and proposed testimony concerning an autologous fascia sling because it amounts to a surgical procedure and is, therefore, not relevant as a matter of law. As with the Burch procedure, I agree with Defendants.

Dr. Rosenzweig's opinions and testimony concerning an autologous fascia sling are excluded because it is a surgical procedure and does not provide an alternative product design. *See Moultrie*, 2020 WL 1249354, at *11 n.20 (excluding testimony concerning autologous fascia sling because it is a "surgical procedure[]"); *Salinero v. Johnson & Johnson*, Civ. 18-23643, 2019 WL 7753453, at *17 (S.D. Fla. Sept. 5, 2019) (same); *Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) (noting plaintiff conceded that native tissue repairs "do not qualify as 'safer alternative designs[]' because they are not products"); *Barnes*, 2019 WL 1353880, at *2 (concluding that "alternative treatment methods" do not qualify as alternative designs). As is true of the Burch

[6] While Defendants generally object to reliance on Dr. Rosenzweig's deposition testimony from another case, *see* ECF No. 89 at 4–5, they do not dispute that his testimony on this point would be admissible at trial. *See Patel*, 941 F.3d at 746–47.

procedure, the mere fact that implanting an autologous fascia sling involves the use of sutures does not convert the procedure into a medical product that could provide an alternative design. *See Heatherman*, 2020 WL 5798533, at *9.

While *Heatherman* permitted an expert to testify that an autologous sling constitutes an alternative design, *see id.*, I do not find its analysis persuasive on this point. *Heatherman* concluded that an autologous fascia sling is a substitute for a mesh sling because the sling is a "tangible thing and not just a process," and the only discernible difference "between an autologous sling and a TVT sling is the substance from which the slings are made—native tissue versus synthetic material." *Id.*; *see also Ellis v. Ethicon, Inc.*, Civ. No. 20-223, 2021 WL 4302339, at *7 (E.D. Tenn. Sept. 21, 2021) (permitting testimony concerning autologous sling as alternative design). Although the sling itself is a "tangible thing," *id.*, the record before me suggests that to create an autologous sling, a surgeon must first harvest tissue from the patient, which is a medical procedure. *Heatherman* further noted that "companies producing these slings refer to them as 'products,'" 2020 WL 5798533, at *9, but there is nothing in the record here indicating that companies sell autologous slings as products or that doing so would be feasible. In this regard, *Heatherman* may have conflated autologous slings and allograft slings, *see id.* (stating that an "allograft" is "another word plaintiff uses for autologous slings"), which are slings created using tissue from another human and which at least one company sells as a product. *See* Rosenzweig Rep. at 50; Rosenzweig *Olszeski* Dep. Tr. 82:10–13. As discussed *infra*, because they are separate products, an allograft sling may provide an alternative design. But the same reasoning does not extend to the implantation of autologous slings, a surgical procedure in which no company's manufactured product—other than sutures—plays any role. Understanding the use of an autologous sling in this manner is also consistent with Dr. Rosenzweig's report, which groups autologous slings together with the Burch procedure as one set of alternatives while grouping allograft slings with other types of mesh slings as another set of alternatives. *See* Rosenzweig Rep.

at 50.

Accordingly, Dr. Rosenzweig's opinions and proposed testimony concerning an autologous fascia sling is not relevant to whether Plaintiff is able to establish an alternative design and is inadmissible for that purpose under Rule 702.

*3. Allograft Sling*

Dr. Rosenzweig's third proposed alternative is an allograft sling. *See* Rosenzweig Rep. at 50. As explained *supra*, an allograft sling is created using tissue harvested from another human. *See* Rosenzweig *Olszeski* Dep. Tr. 82:10–13. Boston Scientific Corporation ("BSC") manufactures and sells an allograft sling product called the Repliform® Tissue Regeneration Matrix. *See* ECF No. 85-3 Ex. D. Defendants move to exclude testimony concerning the allograft sling only on grounds that an allograft is not a substitute for the mesh used in the TVT-O as a matter of law. On this issue, I disagree with Defendants.

Dr. Rosenzweig's opinions and proposed testimony concerning an allograft sling are admissible for purposes of establishing an alternative design. An allograft sling "is a tangible thing and not just a process." *See Heatherman*, 2020 WL 5798533, at *9. It is also a product that at least one company manufactures and that surgeons may implant instead of a synthetic mesh sling as a treatment for SUI. *See* ECF No. 85-3 Ex. D. Based on the record before me, the principal difference between an allograft sling and a TVT-O mesh sling is "the substance from which the slings are made—[human] tissue versus synthetic material." *See Heatherman*, 2020 WL 5798533, at *9 (making the same observation with respect to autologous slings). Defendants do not appear to dispute any of these points. Nor do they contend that an allograft sling is not a safer alternative or was otherwise unavailable when they designed the TVT-O.

Defendants urge the Court to follow other non-binding decisions concluding that allograft slings do not provide alternative designs as a matter of law, but I decline the invitation. *Willet*

precluded testimony concerning allograft slings because they "are regulated by the FDA as human tissues for transplantation" and not as medical devices, as are the Prosima device at issue in *Willet* and the TVT-O sling at issue here. *See* 465 F. Supp. 3d at 907–08 (citing 21 C.F.R. § 1271). But neither Defendants nor *Willet* explain why that distinction is relevant under Michigan law, which requires a "reasonable alternative design" that is "available" and "practicable." *See Peck v. Bridgeport Machines, Inc.*, 237 F.3d 614, 617–18 (6th Cir. 2001). Defendants do not explain why the scheme under which the government regulates a product affects the availability or practicability of the product's design as a potentially safer alternative.

Similarly, *Barnes* concluded that "[b]iologic mesh" constructed using human cadaver dermis is not an alternative to polyester mesh because the products use different materials, *see* 2019 WL 1353880, at *2, but here again, neither Defendants nor *Barnes* explain why the use of different materials alone precludes a product from providing an alternative design. In certain circumstances, substituting materials is one way in which a manufacturer could improve the safety of its product. *See Christoper v. DePuy Orthopaedics, Inc.*, 888 F.3d 753, 767–68 (5th Cir. 2018) (concluding that a metal hip implant could serve as a safer alternative to a plastic hip implant). Other courts recognize that substituting the materials used to construct a pelvic sling does not necessarily render the product "substantially different" and may provide a feasible alternative. *See Pizzitola*, 2020 WL 6365545, at *5 (concluding that "[p]roducts are not substantially different simply because they are comprised of different materials" and that slings made using human tissue are alternatives to mesh slings); *Ellis*, 2021 WL 4302339, at *7 (concluding that "substitut[ing] . . . natural material for synthetic material [does not] make[] the product wholly different" and permitting Dr. Rosenzweig's testimony concerning an allograft sling as an alternative to a TVT-O sling). I agree that in these circumstances, substituting the material used, including using human tissue, to construct a sling does not make the sling a different product such that it cannot provide an alternative design.

Dr. Rosenzweig's proposed testimony concerning an allograft sling as a safer alternative is therefore admissible under Rule 702.

*4. UltraPro Mesh*

Dr. Rosenzweig also proposes a sling that uses a lighter weight, larger pore mesh with less polypropylene, such as UltraPro—an Ethicon product that is used to treat hernias—as another alternative to the TVT-O. *See* Rosenzweig Rep. at 50. UltraPro mesh uses a mix of Prolene mesh, which is the mesh used in a TVT-O and is not absorbable into human tissue, and Monocryl mesh, which is absorbable. *See* ECF No. 72-1 Ex. D, Testimony of Katrin Elbert, *Perry v. Luu*, No. S-1500-CV-279123 (Cal. Sup. Ct. Feb. 11, 2015) ("Elbert *Perry* Test.") Tr. 3293:15–3295:18. Defendants move to exclude Dr. Rosenzweig's opinions concerning UltraPro mesh both as irrelevant—on grounds that UltraPro does not qualify as a feasible alternative design—and based on the reliability of Dr. Rosenzweig's opinion. Neither basis for exclusion is persuasive at this stage.

Testimony related to a sling using UltraPro mesh is relevant to whether Plaintiff is able to establish a feasible alternative design. On this record, the TVT-O and a mesh sling using UltraPro are designs that serve the same purpose but that use different materials. Just as substituting "natural materials for synthetic materials [does not] make[] the product wholly different," *Ellis*, 2021 WL 4302339, at *7, neither does substituting one form of synthetic mesh for another synthetic mesh render the products any less comparable. There is no "difference[] in . . . kind" between the function an UltraPro mesh sling would serve compared to a sling using Prolene mesh. *See Pizzitola*, 2020 WL 6365545, at *5 (concluding the same is true of slings using synthetic and biologic mesh). UltraPro has also been available since the early 2000s, *see* Rosenzweig *Olszeski* Dep. Tr. 86:4–7, and surgeons outside the United States began using it to treat SUI in 2005 at the latest, more than five years before Plaintiff's implantation surgery. *See* ECF No. 85-3 Ex. E, Emrah Okulu *et al.*, *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating*

*effectiveness and complications*, 47 Scandinavian J. of Urology 217, 218 (2013) ("Okulu Study").

The weight of authority from courts around the country favors admitting testimony concerning an UltraPro mesh sling as an alternative to a TVT-O sling in treating SUI. *See Baccaro v. Coloplast Corp.*, Civ. No. 19-1088, 2021 WL 3089202, at *17 (N.D.N.Y. July 22, 2021) (joining the "several courts applying the laws of other states [that] have upheld UltraPro as a hypothetical feasible alternative to allegedly defective vaginal mesh products"); *Ellis*, 2021 WL 4302339, at *7 (permitting Dr. Rosenzweig to testify concerning UltraPro as an alternative design compared to the TVT-O sling); *Williams v. Ethicon, Inc.*, Civ. No. 20-04341, 2021 WL 857747, at *6 (N.D. Ga. Mar. 8, 2021) (permitting Dr. Rosenzweig to testify concerning "a sling with less polypropylene such as Ultrapro" as a feasible alternative design compared to a TVT sling); *Moultrie*, 2020 WL 1249354, at *11 (permitting Dr. Rosenzweig to testify concerning UltraPro as a feasible alternative design compared to the Coloplast Aris sling); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 460–61 (W.D. Pa. 2019) (holding plaintiff could satisfy burden of proof on design defect claim under Pennsylvania law in part because, pursuant to Dr. Rosenzweig's report, UltraPro is a feasible alternative design to the Coloplast Aris sling).

Defendants contend that Ultrapro was not "available" for use in producing the TVT-O, *see* Mich. Comp. Laws § 600.2946(2), because "the FDA has never approved a device using Ultrapro for the surgical treatment of [SUI]." ECF No. 71 at 16–18.[7] There is some support for Defendants' position. *See, e.g.*, *Pizzitola*, 2020 WL 6365545, at *5 (precluding testimony that DynaMesh, another Ethicon product, is a feasible safer alternative to TVT-O in part because "the FDA had not yet cleared the use of th[at] design[]" at the time of the plaintiff's implantation surgery); *Hanifl v. Ethicon, Inc.*,

[7] The FDA has approved UltraPro for use in treating abdominal hernias. *See Baccaro*, 2021 WL 3089202, at *16.

Civ. No. 20-00527, 2021 WL 830183, at *3 (W.D. Mo. Mar. 4, 2021) (precluding testimony on UltraPro as an alternative to another TVT mesh product because the expert "testified that he is not aware of any slings made of Ultrapro or mesh with the same properties as Ultrapro," and "[t]here are . . . no products using these materials available in the United States"); *Wood v. American Med. Sys., Inc.*, Civ. No. 20-00441, 2021 WL 1178547, at *10 (D. Colo. Mar. 26, 2021) (precluding Dr. Rosenzweig from testifying that UltraPro is a feasible alternative to another pelvic mesh product because, according to his testimony, UltraPro is not "available in the United States for treatment of [SUI]"). Notably, *Pizzitola* turned more specifically on the fact that the "design[] had not been used or tested by hospitals at the time the . . . TVT-O sling w[as] implanted," which *Pizzitola* attributed to the fact that the "FDA had not cleared . . . the[] design[]." *Id.* Here, Plaintiff notes that UltraPro has been available since the early 2000s and that surgeons outside the United States began implanting UltraPro mesh as a treatment for SUI in 2005. *See* Rosenzweig *Olszeski* Dep. Tr. 86:4–10; Okulu Study at 218.

But even construing *Pizzitola* and the other decisions Defendants cite as requiring FDA approval in all circumstances, I do not find those decisions persuasive. Defendants do not cite to any authority under Michigan law interpreting availability to require FDA approval. Courts also regularly refer to a proposed alternative as a "hypothetical design" and not necessarily one that is already on the market. *See, e.g.*, *Zaremba v. Gen. Motors Corp.*, 360 F.3d 355, 359 (2d Cir. 2004); *Baccaro*, 2021 WL 3089202, at *16 (citing *Urena v. ConAgra Foods, Inc.*, 2020 WL 3051558, at *9 (E.D.N.Y. June 8, 2020)); *see also Restatement (Third) of Torts* Ch. 1 § 2 cmt. d ("If the plaintiff introduces expert testimony to establish that a reasonable alternative design could practically have been adopted, a trier of fact may conclude that the product was defective notwithstanding that such a design was not adopted by any manufacturer, or even considered for commercial use, at the time of sale."); *Hollister v. Dayton Hudson Corp.*, 5 F. Supp. 2d 530, 533 (E.D. Mich. 1998), *rev'd in part on other*

*grounds*, 201 F.3d 731 (6th Cir. 2000) (explaining that "[a]lthough Michigan has not adopted the Proposed Final Draft of the Restatement (Third) of Torts: Product Liability § 2 (April 1, 1997), the Michigan risk-utility test is consistent with the principles of section 2(b)"). Moreover, interpreting availability to require an FDA-approved product that implements the proposed alternative design would enable companies to avert liability by merely refraining from seeking FDA approval for designs they know to be safer, which would subvert the purpose underlying design defect law. *See Restatement (Second) of Torts* Ch. 1 § 2 cmt. a ("The emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products."). Ultimately, Plaintiff bears the burden of proving that her proposed alternative design is safer and feasible, and that finding—regardless of whether the FDA has approved the design—is a central element that a factfinder must decide. *See Croskey*, 532 F.3d at 516. For these reasons, I do not interpret Michigan law to require FDA approval of a proposed alternative design, and I join the many other courts—including the MDL court—that have rejected Defendants' position under the laws in other states. *See, e.g.*, *Baccaro*, 2021 WL 3089202, at *17; *Bell v. Ethicon, Inc.*, Civ. No. 20-3678, 2021 WL 1111071, at *7 (S.D. Tex. Mar. 23, 2021); *Ellis*, 2021 WL 4302339, at *7; *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2020 WL 1060970, at *3 (S.D. W. Va. Feb. 13, 2020).

Based on the record before me, Dr. Rosenzweig's opinions and proposed testimony regarding UltraPro would also be reliable. Dr. Rosenzweig's report opines that UltraPro is a safer alternative compared to the Prolene mesh used in the TVT-O because a mesh "sling that uses less polypropylene[, such as UltraPro,] . . . reduces the risk of injury to the soft tissues of the pelvis and limb and thereby reduce[s] the risk [of] injury to or irritation of the pudendal nerve." *Id.* Dr. Rosenzweig also opines that a "lighter weight, larger pore mesh[] reduce[]s the risk of acute injury or irritation to adjacent nerves at the time of implant and reduce[s] secondary nerve entrapment acutely and years later[,] as there is less degradation, mesh shrinkage, and scarification." *Id.* These

characteristics of UltraPro would address key deficiencies Dr. Rosenzweig identified in the Prolene mesh used in the TVT-O. *See* Rosenzweig Gen. TVT-O Rep. at 27–32; *see also Baccaro*, 2021 WL 3089202, at *16 (reaching same conclusion regarding UltraPro as an alternative to a synthetic mesh product used to treat SUI that is similar to the TVT-O). As support for his position, Dr. Rosenzweig cites to a study conducted in Turkey that compared the use of UltraPro to that of Ethicon's Prolene soft mesh and Vypro mesh, another Ethicon product, in treating SUI. *See* ECF No. 85-3 Ex. B, Deposition of Bruce A. Rosenzweig, M.D. ("Rosenzweig Dep.") Tr. 80:17–81:15; Okulu Study. The Okulu Study concluded that the use of UltraPro mesh yielded lower complication rates and was at least equally effective in treating SUI compared to Prolene soft mesh and Vypro mesh. *See* Okulu Study at 222–23.

Defendants contend that Dr. Rosenzweig's opinion is not reliable due to various issues with his reliance on the Okulu Study, none of which is dispositive on the existing record. While Defendants cite literature in their Reply brief showing a lower incidence of urinary retention with the TVT-O compared to that associated with UltraPro in the Okulu Study, *see* ECF No. 88 at 10 (citing Schimpf, *et al.*, *Sling Surgery for stress urinary incontinence in women: a systematic review and metaanalysis*, Am. J. Obstetric Gynecology 2014;211:71.e1-27 at 71.e9), the Okulu Study measured multiple postoperative complications beyond retention, and the study concludes that UltraPro had lower complication rates across each metric compared to Prolene mesh. *See* Okulu Study at 222. Defendants do not contend that the TVT-O had lower complication rates than UltraPro across each of these metrics. Thus, the literature to which Defendants cite does not negate Dr. Rosenzweig's opinion based on the Okulu Study that UltraPro mesh could provide a safer alternative. To the extent that the Schimpf study undermines any portion of Dr. Rosenzweig's opinion, such discrepancies are factual matters that a jury must decide and go to weight rather than admissibility. *See Heatherman*, 2020 WL 5798533, at **9–10 (concluding that a "jury is best suited" to make "fact-intensive

determination[s]" pertaining to safer alternative designs that "depend heavily on medical information"); *Ellis*, 2021 WL 4302339, at *7.

Defendants also note that the surgeries analyzed in the Okulu Study used a softer form of Prolene mesh, and employed different needles and incisions, compared to the TVT-O. *See* ECF No. 71 at 19–20. But the comparison between UltraPro and a softer Prolene mesh than the Prolene used in a TVT-O tends to support Dr. Rosenzweig's position, as he opines that "lighter weight, larger pore meshes reduce the risk" of "degradation, mesh shrinkage, and scarification." *See* Rosenzweig Rep. at 50; Rosenzweig Gen. TVT-O Rep. at 27–32. Defendants may raise these points on cross-examination, *see Ellis*, 2021 WL 4302339, at *7, but they do not render unreliable Dr. Rosenzweig's broader opinion as to the comparative safety of UltraPro mesh. And although the Okulu Study does not conduct a separate cost analysis, *see* ECF No. 71 at 19, UltraPro mesh has been available for other surgical applications since the early 2000s, generally supporting its feasibility as an alternative design for purposes of admissibility. To the extent that the feasibility and cost associated with using UltraPro mesh to treat SUI are in question, these are factual issues the jury must resolve and which Defendants are free to raise at trial. *See Heatherman*, 2020 WL 5798533, at **9–10.

Defendants rely on *Willet* in challenging Dr. Rosenzweig's opinion that UltraPro provides a safer alternative, but *Willet* is distinguishable in the circumstances at issue here. *Willet* addressed proposed testimony that Prosima+M, another mesh product using UltraPro that Ethicon began developing as a treatment for pelvic organ prolapse—but that it ultimately abandoned—provides a feasible safer alternative to Prosima, an Ethicon product that uses Prolene mesh. *See* 465 F. Supp. 3d at 901–02. The court precluded the expert's testimony due to a "lack of scientifically adequate evidence to support a reliable expert opinion" and, in particular, the absence of testing or medical literature showing that Prosima+M would be a safer alternative. *See id.* at 908–09. In contrast, here, Dr. Rosenzweig cites to the Okulu study as evidence that UltraPro yields improved efficacy and

safety compared to Prolene mesh in treating SUI. *Cf. id.* at 909 (noting that the expert "cites peer reviewed publications about problems with small pore meshes, but none showing that Prosmia+M . . . would be safer").[8]

Although on the existing record I find that Dr. Rosenzweig's opinions and proposed testimony concerning UltraPro mesh are admissible, I also agree with Defendants that there are gaps in the evidence supporting admissibility. Dr. Rosenzweig's opinion relies heavily on the Okulu Study, but there is no discussion of whether the Okulu Study is peer reviewed, an important consideration, particularly where the study is integral to the expert's opinion. *See Pineda*, 520 F.3d at 247; *Willet*, 465 F. Supp. 3d at 908–09. Defendants have also identified other dissimilarities between the products compared in the Okulu Study and those at issue here that render the study an imperfect fit for purposes of establishing a safer alternative. While these issues do not render Dr. Rosenzweig's opinions and proposed testimony inadmissible on the existing record, the parties are on notice that the Court retains the authority to revisit the relevance and reliability of Dr. Rosenzweig's testimony concerning UltraPro mesh *sua sponte* at trial. *See, e.g.*, *Miller v. Baker*

[8] Defendants also emphasize that the Okulu Study was not published until 2013, whereas Plaintiff's implantation surgery occurred in 2011. *See* ECF No. 71 at 19. However, they do not cite to any authority for the proposition that, for purposes of establishing a safer alternative design, a study supporting an expert's opinion must be available before the plaintiff receives the product in question. The statute provides that the safer design itself must be available. *See* Mich. Comp. Laws § 600.2946(2). Here, UltraPro was available beginning in the early 2000s, surgeons began using UltraPro to treat SUI outside the United States beginning in 2005, and the Okulu Study ultimately demonstrated potential safety benefits of UltraPro compared to Prolene mesh. *See* Okulu Study at 218; Rosenzweig *Olszeski* Dep. Tr. 86:4–10. Moreover, Ethicon sought FDA approval for a device that used UltraPro mesh as a treatment for SUI in 2010, and it sought to develop that product in order to "leave less mesh in the patient." *See* ECF No. 72-1 Ex. C, Ltr. from FDA to Susan Lin, Manager of Regulatory Affairs at Ethicon Women's Health & Urology (Sept. 11, 2011) ("FDA UltraPro Letter"); Elbert *Perry* Test. Tr. 3294:21–3295:18. Ethicon ultimately withdrew its application after receiving follow-up questions from the FDA and experiencing difficulties during cadaver testing with placement of the mesh using a transobturator procedure. *See* FDA UltraPro Letter; Elbert *Perry* Test. Tr. 3296:17–3300:10. Nevertheless, there is evidence that Ethicon was aware of the potential benefits of using UltraPro mesh to treat SUI before 2011.

*Implement Co.*, 439 F.3d 407, 413 (8th Cir. 2006) ("A district court's *Daubert* inquiry need not take any specific form, and its *sua sponte* consideration of the admissibility of expert testimony is permissible so long as the court has an adequate record on which to base its ruling."); *Kiersten v. Parks Corp.*, 159 F.3d 1065, 1067 (7th Cir. 1998) ("We have not required that the *Daubert* inquiry take any specific form and have, in fact, upheld a judge's *sua sponte* consideration of the admissibility of expert testimony."); *Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 97 (D. Conn. 2014) (explaining that the court has "the authority to raise *Daubert* concerns *sua sponte*" and noting that the court used such authority at trial); *Fellner v. Supreme Corp.*, Civ. No. 92-3680, 1995 WL 79787, at *4–5 (D.N.J. Feb. 21, 1995) (concluding district court has the power to hold a *Daubert* "hearing outside the presence of the jury to determine the admissibility of expert testimony"); *Schloss v. Sears Roebuck and Co.*, Civ. No. 04-2423, 2006 WL 8459575, at *3 (E.D. Pa. Sept. 27, 2006) (noting that the Third Circuit had "not directly addressed . . . whether a trial court may make a *Daubert* determination *sua sponte*" but concluding that the court possessed such authority based on cases from other circuits); *cf. Henry v. St. Croix Allumina, LLC*, 572 F. App'x 114, 119 (3d Cir. 2014) (holding district court did not abuse "its discretion in declining to hold a *Daubert* hearing *sua sponte*"). Accordingly, Dr. Rosenzweig's opinions concerning UltraPro mesh as a feasible safer alternative are conditionally admissible under Rule 702.

*5. Retropubic Sling and Retropubic Sling with UltraPro Mesh*

Finally, Dr. Rosenzweig proposes a retropubic sling and a retropubic sling using UltraPro mesh as safer alternatives to the TVT-O. *See* Rosenzweig Rep. at 50–51. A retropubic sling differs from a TVT-O sling in that implanting a retropubic sling does not require the use of a transobturator surgical procedure, in which the sling must "run through the obturator internus muscle as it passes into the groin." *See* Rosenzweig Rep. at 10, 50. According to Dr. Rosenzweig, the pudendal nerve is "adjacent to the obturator internus muscle," and running a mesh sling through the obturator muscle

can cause obturator internus muscle spasm and muscle fibrosis, which can lead to entrapment of the pudendal nerve and pudendal neuralgia—the diagnosis Plaintiff received following her TVT-O implantation. *See id.* at 10–11, 33, 36. Dr. Rosenzweig opines, based on medical studies, that a retropubic sling would "substantially reduce the risk of pudendal neuralgia" because it does not pierce the obturator muscle and enter the leg. *See id.* at 50–51; Rosenzweig Dep. Tr. 83:22–84:6.[9] He also testified that a retropubic sling "would have eliminated the risk of the development of obturator internus muscle spasms," from which Plaintiff suffered. *See* Rosenzweig Dep. Tr. 84:7–24.

Defendants move to exclude Dr. Rosenzweig's opinions and proposed testimony concerning a retropubic sling primarily because Ethicon already offers such a product—the Gynecare TVT Sling Retropubic System (the "TVT"). *See* ECF No. 71 at 22. It claims that Dr. Nowak's decision to use the TVT-O rather than the TVT is a matter of medical judgment and is irrelevant to whether the TVT provides a safer alternative design. *Id.* I disagree. Courts have permitted testimony that a retropubic sling provides a safer alternative to a transobturator sling, even where the same company manufactures both products. *See Campbell v. Boston Scientific Corp.*, 882 F.3d 70, 79 (4th Cir. 2018) (upholding reliance on testimony regarding a study comparing BSC's retropubic TVT mesh product with its transobturator TVT-O product, which "found no difference in cure rates between the two

[9] In his deposition, Dr. Rosenzweig cited to two studies—the "[Trial of Midurethral Slings] ["TOMUS"] 1 and TOMUS 2"—for the proposition that using a retropubic sling rather than a TVT-O sling would have "significantly reduced the risk of pudendal neuralgia," but he did not elaborate and there were no further questions regarding the studies. *See* Rosenzweig Dep. Tr. 83:22–84:6. In his report, Dr. Rosenzweig also cites to specific studies that, in his opinion, demonstrate that the TVT-O may cause pudendal neuralgia. *See* Rosenzweig Rep. at 12 (citing J. Paulson and J. Baker, *De novo pudendal neuropathy after TOT-O surgery for stress urinary incontinence*, 15 JSLS (3), 326–30 (July–Sept. 2011); M. Possover and N. Lemos, *Risks, symptoms, and management of pelvic nerve damage secondary to surgery for pelvic organ prolapse: a report of 95 cases*, 22 Int'l Urogynecology J. (12), 1485–90 (Dec. 2011)). Defendants do not raise any specific objections to this literature in their moving papers.

devices but more groin pain among women who received the [TVT-O]");[10] *Ellerbee v. Ethicon, Inc.*, Civ. No. 20-1514, 2020 WL 4815818, at *3 (M.D. Fla. Aug. 19, 2020) (permitting expert to testify that a retropubic synthetic sling is a safer alternative to the Ethicon TVT-O).

Defendants also emphasize that Dr. Rosenzweig's report proposes a retropubic sling while characterizing it as "defective." *See* ECF No. 71 at 22; Rosenzweig Rep. at 50. I agree that Dr. Rosenzweig's report is vague on this point, and neither party asked Dr. Rosenzweig to elaborate during his deposition. *See* Rosenzweig Dep. Tr. 26:11–30:11, 83:22–86:7, 89:21–90:10. However, there is a reasonable inference that Dr. Rosenzweig characterized a retropubic sling as "defective" insofar as it uses polypropylene mesh, a material he believes is problematic for other reasons. *See* ECF No. 85 at 15; Rosenzweig Gen. TVT-O Rep. at 11–34. In that regard, Dr. Rosenzweig's report implies that both the TVT-O and a TVT retropubic sling present a similar risk of complications stemming from the use of the polypropylene mesh, *see* Rosenzweig Dep. Tr. 83:22–84:3 (discussing "retropubic sling made of the same polypropylene material as the TVT-O"), but the retropubic sling would have been safer for Plaintiff overall because the underlying procedure would have eliminated the risk of obturator internus muscle spasms and substantially reduced the risk of pudendal neuralgia. This explanation is consistent with Dr. Rosenzweig's deposition testimony, in which he testifies that a transobturator procedure creates a risk of obturator internus muscle spasm and pudendal neuralgia because the device passes through the obturator internus muscle, which does not occur when implanting a retropubic sling. *See* Rosenzweig Dep. Tr. 27:13–28:25. Thus, on this record, Dr. Rosenzweig's description of a retropubic sling as "defective" does not render his testimony on that

[10] Although *Campbell* does not refer to a retropubic sling explicitly, in context, the testimony it cites on this point concerns a comparison between a retropubic TVT sling and a transobturator TVT-O sling. *See* Testimony of Bruce A. Rosenzweig, M.D., *Tyree* et al. *v. Boston Scientific Corp.*, Civ. No. 12-08633 (S.D. W. Va. Nov. 4, 2014), ECF No. 484, Tr. 458:20–462:13.

alternative design irrelevant or unreliable. *See Phillips v. Hardware Wholesalers, Inc.*, 762 F.2d 46, 48–49 (6th Cir. 1985) (applying Michigan law and concluding that where expert presents alternatives that are "available, reasonably efficient, and safe," but testifies to certain "disadvantages associated with the alternatives" and that "he would not necessarily incorporate the alternative designs he had described, . . . [i]t is the province of the jury, not the expert, to weigh the advantages and disadvantages that the expert has identified") (quotations omitted).

Defendants also suggest that Dr. Rosenzweig's testimony is inadmissible because he opines that using a retropubic sling would have prevented only one of Plaintiff's injuries—obturator internus muscle spasms. *See* ECF No. 88 at 12. In particular, Dr. Rosenzweig testified that a retropubic sling would not have eliminated the risk of dyspareunia, vaginal pain, and urinary dysfunction. *See* Rosenzweig Dep. Tr. 89:21–90:10. But Dr. Rosenzweig also opines that a retropubic sling would "substantially reduce the risk of pudendal neuralgia," another injury Plaintiff incurred. *See* Rosenzweig Rep. at 33, 51. Courts applying Michigan law repeatedly characterize the risk-utility inquiry as whether the proposed alternative "would have *reduced* the foreseeable risk of harm posed by [the] defendant's product." *Hollister*, 201 F.3d at 738 (emphasis added); *Palatka v. Savage Arms, Inc.*, 535 F. App'x 448, 455–56 (6th Cir. 2013) (admitting expert testimony that alternative design would have "reduced the likelihood" of the issue that caused the plaintiff's injury on a design defect claim under Michigan law); *Reeves v. Cincinnati, Inc.*, 176 Mich. App. 181, 187–88 (1989) (characterizing the inquiry as whether an alternative "would have been effective as a reasonable means of *minimizing* the foreseeable risk of danger") (emphasis added). Here, Dr. Rosenzweig opines that a proposed alternative would have eliminated or substantially reduced the risk of two prominent injuries Plaintiff sustained, and there is no evidence at this stage that the alternative would have increased the risk of other injuries compared to the product Plaintiff received. Thus, Dr. Rosenzweig has proposed an alternative that would have reduced the risk of harm to Plaintiff such that his

opinions concerning that alternative are admissible. *See Hollister*, 201 F.3d at 738.

Notwithstanding my decision to admit Dr. Rosenzweig's opinions and proposed testimony concerning retropubic slings, the issue remains that Dr. Rosenzweig fails to explain in detail his description of a retropubic sling as "defective." Should it come to light that the defect he identifies differs from what is discussed in this Opinion, I reserve the right to revisit the issue *sua sponte*. *See Kiersten*, 159 F.3d at 1067; *Fraser*, 992 F. Supp. 2d at 97. Accordingly, Dr. Rosenzweig's opinions that a retropubic sling is a safer alternative to the TVT-O are conditionally admissible under Rule 702.[11]

*6. Additional Alternatives*

In her Opposition, Plaintiff contends that Defendants failed to address other safer alternatives Dr. Rosenzweig proposed: the Flam technique, which is an alternative implantation procedure; a sling made of Ethicon's PVDF mesh; and non-UltraPro lighter weight, larger pore mesh. *See* ECF No. 85 at 16. However, I agree with Defendants that Plaintiff has failed to meet her burden to show that testimony on these alternatives would be relevant and reliable, as Dr. Rosenzweig does not offer any of these procedures or devices as alternatives that would have reduced the likelihood of Plaintiff's specific injuries. *See* Mich. Comp. Laws § 600.2946(2) (providing that the alternative must prevent the plaintiff's injury).

In his case-specific report, Dr. Rosenzweig discusses the six alternatives identified *supra* as alternatives that would have been feasible and safer "for Ms. Dandy," and he does so on two occasions in the same report. *See* Rosenzweig Rep. at 19–20, 50–51. While he discusses the Flam

[11] Defendants do not specifically challenge testimony as to the retropubic sling with UltraPro mesh other than by challenging a retropubic sling and UltraPro mesh independently, so I do not address that alternative in detail here. Nevertheless, for the reasons discussed *supra* concerning UltraPro mesh and retropubic slings, testimony concerning a retropubic sling using UltraPro mesh is admissible as well.

technique in the "General Opinions" section of his case-specific report, *see id.* at 4–5, he does not discuss the use of that procedure in reference to Plaintiff or explain why it would have been safer for her. *Compare* Rosenzweig Rep. at 4 (noting that the "the Flam Technique would substantially reduce the risk of injury or irritation to the obturator nerve"), *with id.* at 49 (noting that Plaintiff's injuries are "pelvic pain, hip pain, pelvic floor muscle spasm, vaginal pain, dyspareunia, recurrent UTIs, voiding dysfunction, mixed UI and pudendal neuralgia"). Likewise, in the report he submitted in the pelvic mesh MDL, Dr. Rosenzweig notes that a "midurethral sling made from PVDF (e.g., DynaMesh) . . . would have also been a safer alternative." *See* Rosenzweig Gen. TVT-O Rep. at 110. But again, Dr. Rosenzweig does not explain whether this alternative would have reduced the likelihood of Plaintiff's injuries. *See id.* at 110. He also explains that the alternatives proposed in his MDL report "depend on the patient, patient's lifestyle, patient's medical history, and the injuries the patient suffers from." *Id.* at 109. And beyond UltraPro, Dr. Rosenzweig does not propose any particular lighter weight, larger pore mesh design that was "available" and "feasible," *see* Mich. Comp. Laws § 600.2946(2), as is Plaintiff's burden to show. *Hollister*, 201 F.3d at 739.

Accordingly, on the existing record, Dr. Rosenzweig's opinions and proposed testimony concerning the additional alternatives Plaintiff raises in her Opposition are not admissible under Rule 702.

## IV. MOTION FOR SUMMARY JUDGMENT

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also* Fed. R. Civ. P. 56(c). A court evaluating a motion for summary judgment must view the facts in favor of the non-moving party and draw all reasonable inferences in favor of the same. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574,

587 (1986). A factual dispute is genuine only if there is "a sufficient evidentiary basis on which a reasonable [factfinder] could find for the nonmoving party," and it is material only if it has the ability to "affect the outcome of the suit under governing law." *Kaucher v. Cty. of Bucks*, 455 F.3d 418, 423 (3d. Cir. 2006); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment. *Anderson*, 477 U.S. at 248. "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the nonmoving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d. Cir. 2004) (quoting *Anderson*, 477 U.S. at 255).

The initial burden is on the moving party to show the basis for its motion. *Celotex Corp.*, 477 U.S. at 323. When the moving party would not bear the burden of persuasion at trial, "the burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Id*. at 325; *Conoshenti v. Public Serv. Elec. & Gas Co.*, 364 F.3d 135, 140 (3d Cir. 2004). Once the movant sufficiently supports its motion pursuant to Rule 56(c), the burden shifts to "the nonmoving party to go beyond the pleadings and by [its] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Id*. at 324 (quoting Fed. R. Civ. P. 56(e)). The nonmoving party must "point to concrete evidence in the record which supports each element of its case," *Black Car Assistance Corp. v. New Jersey*, 351 F. Supp. 2d 284, 286 (D.N.J. 2004), presenting "more than just 'bare assertions, conclusory allegations or suspicions.'" *Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d. Cir. 2005) (quoting *Celotex Corp.*, 477 U.S. at 325), *abrogation on other grounds recognized by Office of Dist. Attorney Erie Cty.*, 751 F. App'x 196, 199–200 (3d Cir. 2018). When deciding a motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter; instead, the court

merely determines whether there is a genuine issue of material fact for trial. *Anderson*, 477 U.S. at 249. The moving party is entitled to judgment as a matter of law where the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which . . . [it has] the burden of proof." *Celotex Corp.*, 477 U.S. at 322–23.

Here, Defendants move for summary judgment on Plaintiff's negligence claims for design defect, manufacturing defect, and failure to warn. Because Plaintiff does not oppose the motion as to her manufacturing defect claim, *see* ECF No. 83 at 5 n.1, that claim is dismissed.

**A. Design Defect**

Defendants move for summary judgment on Plaintiff's design defect claim only on grounds that Plaintiff has failed to propose a legally sufficient safer alternative design. *See* ECF No. 73 at 17. On Defendants' *Daubert* Motion, I concluded that the Burch procedure and an autologous fascia sling do not constitute safer alternatives as a matter of law, thereby precluding Dr. Rosenzweig's opinions and proposed testimony concerning those proposed alternative designs. Accordingly, Plaintiff cannot survive summary judgment by offering the Burch procedure or an autologous fascia sling as safer alternatives. *See Hendrian v. Safety-Kleen Sys.*, Civ. No. 08-14371, 2015 WL 4770966, at *5 (E.D. Mich. Aug. 13, 2015) (citing *Maldonado v. Otis Elevator Co.*, No. 212495, 1999 WL 33409923, at *2 (Mich. Ct. App. Nov. 30, 1999) ("Expert testimony is required to establish the design defect."). However, I concluded that an allograft sling, a transobturator sling using UltraPro mesh, a retropubic sling, and a retropubic sling using UltraPro mesh, could qualify as safer alternatives as a matter of law. I also concluded, based on the existing record, that Dr. Rosenzweig's testimony concerning these alternatives would be reliable and relevant to the facts at issue. *See Paoli*, 35 F.3d at 742; *Schiff*, 602 F.3d at 172–73.

Defendants have therefore failed to demonstrate that "there is no genuine issue as to any material fact and that [they are] entitled to a judgment as a matter of law." *Celotex*, 477 U.S. at 322.

Plaintiff has proposed designs that could qualify as safer alternatives as a matter of law, which is the only grounds upon which Defendants move for summary judgment against Plaintiff's design defect claim. *See* ECF No. 73 at 17 (contending that none of Plaintiff's "proposed alternatives is legally sufficient . . . to establish her design defect claim"). And Plaintiff is able to introduce expert testimony concerning these designs, as required under Michigan law. *See Hendrian*, 2015 WL 4770966, at *5; *Peak v. Kubota Tractor Corp.*, 924 F. Supp. 2d 822, 831 (E.D. Mich. 2013) (citing *Owens*, 414 Mich. at 430). Accordingly, Defendants' Motion for Summary Judgment on Plaintiff's design defect claim is denied.

**B. Failure to Warn**

To establish a negligence claim for failure to warn under Michigan law, "a plaintiff must prove: (1) the defendant owed a duty to the plaintiff; (2) the defendant breached that duty; (3) the defendant's breach was a proximate cause of the plaintiff's injuries; and (4) the plaintiff suffered damages." *Croskey*, 532 F.3d at 515 n.2; *Avendt v. Covidien, Inc.*, 262 F. Supp. 3d 493, 520 (E.D. Mich. 2017) (citing *Warner v. Gen. Motors Corp.*, 137 Mich. App. 340, 348 (1984)). "A manufacturer has a duty to warn if it has actual or constructive knowledge of a danger, which is not obvious to users, and the manufacturer failed to use reasonable care in informing users of the danger or the facts tending to make the condition dangerous." *Croskey*, 532 F.3d at 515 n.2.

Michigan follows the learned intermediary doctrine in failure to warn cases involving medical devices. *See Avendt*, 262 F. Supp. 3d at 521 (citing *Brown v. Drake-Willock, Intern., Ltd.*, 209 Mich. App. 136, 146 (1995)). Under this doctrine, a manufacturer "has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the [device] which the manufacturer knows or should know to exist." *See Brown*, 209 Mich. App. at 148 (quoting *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 88 (1979)). To establish proximate cause under the learned intermediary, the plaintiff must "show that 'an adequate warning would have prevented the plaintiff's injury by

altering the prescribing doctor's conduct or that the doctor might have heeded the warning.'" *Tice v. Zimmer Holdings, Inc.*, Civ. No. 15-134, 2015 WL 4392985, at *6 (W.D. Mich. July 15, 2015) (quoting *Nichols v. Clare Cmty. Hosp.*, 190 Mich. App. 679, 684 (1991)).

Here, Plaintiff has failed to establish proximate cause because there is no evidence that Dr. Nowak would have altered his recommendation to Plaintiff based on the revised warnings Plaintiff proposes. During Dr. Nowak's testimony, Plaintiff's counsel asked questions concerning reference to "[p]ain which may be severe and chronic" in the Adverse Reactions section of a 2019 version of the TVT-O IFU, which did not appear in the 2011 IFU associated with the TVT-O implanted in Plaintiff. *See* Nowak Dep. Tr. 77:13–79:11. Plaintiff's counsel also mentioned an adverse reaction referenced in the 2019 IFU involving "[n]euromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area," which did not appear in the 2011 IFU either. *See id.* Tr. 81:12–82:5. In response to questions on those issues, Dr. Nowak testified:

> Q: . . . if you had the information that an adverse reaction to this was pain that may be severe and chronic, then you could have imparted that information to Ms. Dandy, right?
>
> A: Correct.
>
> Q: . . . Had you known that neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur, would you have -- if you had had that information in your IFU back then, would you have been able to impart that to Ms. Dandy?
>
> MS. CRAWFORD: Objection.
>
> A: Yes.

*See id.* Tr. 85:8–12. In addition, Dr. Nowak testified that he would "[p]robably not" use a product if he "thought there had been no clinical trials proving its safety and efficacy." *See id.* Tr. 114:8–11.

Plaintiff has not demonstrated a genuine dispute as to proximate cause. At most, there is a reasonable inference that Dr. Nowak would have informed Plaintiff of the additional risks referenced

in his deposition had they appeared in the 2011 IFU. But this does not mean Dr. Nowak would have altered his recommendation to Plaintiff had he seen those warnings. To the contrary, Dr. Nowak testified that he would not have done "anything differently . . . with respect to the recommendation for a TVT-O for [Plaintiff] in 2011." *See id.* Tr. 172:1–5. He also testified that he believed that the TVT-O is a safe and effective product, both in 2011 and at the time of his deposition. *See id.* Tr. 171:14–23. Because Plaintiff does not identify any additional evidence that Dr. Nowak would have altered his recommendation to Plaintiff based on revised warnings, there is no genuine dispute as to proximate cause. *See LaBarre v. Bristol-Myers Squibb Co.*, Civ. No. 06-6050, 2013 WL 144054, at *10 (D.N.J. Jan. 11, 2013), *aff'd*, 544 F. App'x 120 (3d Cir. 2013). Defendants' Motion for Summary Judgment on Plaintiff's failure-to-warn claim is granted.

## V. CONCLUSION

For the reasons set forth above, Defendants' *Daubert* Motion is **GRANTED** in part and **DENIED** in part, and their Motion for Summary Judgment is **GRANTED** in part and **DENIED** in part. The Motion for Summary Judgment is granted with respect to the manufacturing defect and failure-to-warn claims, and it is denied with respect to the design defect claim.

Date: April 29, 2022

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge